REMARKS/ARGUMENTS

I. STATUS OF THE APPLICATION

Claims 1-41 are presently pending and stand rejected. By way of this response, fourteen (14) claims have been amended and twenty-two (22) claims have been cancelled. Claim 42 was previously withdrawn in response to the Election/Restriction mailed on March 17, 2008, and is cancelled herein. Applicants respectfully submit that no new matter has been added by way of this amendment.

Support for the amendment to Claim 1 can be found at least at paragraphs 0145 and 0152 – 0156 in the application as published (US 20050118242), and in Claims 1 and 9 as originally filed.

Claims 6, 11-15, 17-18, 22, and 24-25 have been amended to change the claim dependency for which support can be found in Claims 6, 11-15, 17-18, 22, and 24-25, respectively, as originally filed.

Support for the amendment to Claim 9 can be found at least at paragraphs 0145 and 0195 in the application as published (US 20050118242), and in Claim 9 as originally filed. Further, Claim 9 has been amended to change the claim dependency.

Support for the amendment to Claim 28 can be found at least at paragraphs 0159 in the application as published (US 20050118242), and in Claim 28 as originally filed. Further, Claim 28 has been amended to change the claim dependency.

Rejoinder of Claim 42

Pursuant to 37 C.F.R. § 1.141 and MPEP §§ 809 and 821.04, Applicants specifically reserve the right of rejoinder of Claim 42 in the event that a generic or linking claim is deemed allowable and Claim 42 are dependent from such allowed claim or otherwise contain all of the limitations of the allowed generic or linking claim.

II. THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (SCOPE OF ENABLEMENT), SHOULD BE WITHDRAWN

Claims 1-41 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement in that the specification "does not reasonably provide enablement for a method to prevent depressive disorder." Preliminarily, Examiner admits that "treating is inclusive of various administrative timing schemes and thus provides adequate coverage for all reasonably successful therapies (prophylactic or active)" (internal quotes removed). Without admitting or conceding in any manner that rejected Claims 1-41 fail to comply with 35 U.S.C. § 112, first paragraph, and solely to expedite the prosecution of the present application, Claims 1 and 29 have been amended to remove "preventing" from the preamble of the claims as suggested by the Examiner. Applicants respectfully submit that this rejection is now moot, and that no new matter has been presented by way of this amendment. Withdrawal of the rejections of claims 1-41 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

III. THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH (SCOPE OF ENABLEMENT), SHOULD BE WITHDRAWN

Claims 2-28 and 30-31 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to "reasonably provide enablement for a method of treating or reducing the risk of developing a depressive disorder using the **prodrug** or **derivative** of testosterone" (emphasis original). Applicants respectfully traverse this rejection. Without admitting or conceding in any manner that rejected claims 2-28 and 30-31 fail to comply with 35 U.S.C. § 112, first paragraph, and solely to expedite the prosecution of the present application, Claims 2, 3, 30 and 31 have been cancelled. Applicants respectfully submit that this rejection is now moot, and that no new matter has been presented by way of this amendment. Withdrawal of the rejections of claims 2-28 and 30-31 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

IV. THE CITED REFERENCE DOES NOT ANTICIPATE ANY OF THE CLAIMS UNDER 35 U.S.C. § 102(e)

Claims 1-11, 15-23, 25-38 and 41 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Dudley et al. (U.S. 6,503,894 B1, hereinafter "'894 Patent"). Applicants respectfully traverse this rejection. Section 102(e) states in relevant part:

> "A person shall be entitled to a patent unless - (e) the invention was described in (1) an application for patent, published under section 122(b), ***by another*** filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent ***by another*** filed in the United States before the invention by the applicant for patent. (emphasis added)."

"By another" means a different inventive entity. An "inventive entity is different if not all inventors are the same." M.P.E.P. § 2136.04. Applicant respectfully submits that the present application and the '894 Patent share the same inventive entity; namely, Robert E. Dudley and Dominique Drouin. The pending application names Robert E. Dudley and Dominique Drouin as the inventors. Similarly, in the '894 Patent, Robert E. Dudley and Dominique Drouin are listed as inventors. A Certificate of Correction in the '894 Patent to change the listing of inventors to Robert E. Dudley and Dominique Drouin was granted on May 22, 2007. As such, both the present application and the '894 Patent have the same inventive entity. Consequently, the '894 Patent is not "by another" and thus cannot be a basis for a 35 U.S.C. § 102(e) rejection.

For the foregoing reasons, Applicants submit that no *prima facie* case of anticipation has been established and respectfully requests withdrawal of this rejection.

V. THE COMBINED REFERENCES CITED IN THE MAY 14, 2008 OFFICE ACTION DO NOT RENDER ANY OF THE CLAIMS UNPATENTABLE UNDER UNDER 35 U.S.C. § 103(a)

The Office action made rejections under 35 U.S.C. § 103(a) of Claims 12-14 over U.S. Patent No. 6,503,894 B1 ("Dudley") as applied to Claims 1-11, 15-23, 25-38 and 41, and Claims 24 and 39-40 over Dudley as applied to Claims 1-23 and 25-38 in view of U.S. Patent No. 5,550,107 ("Labrie"). Applicant respectfully traverses these rejections and requests that the rejections be withdrawn in light of the arguments set forth below.

As argued above, Applicant submits that Dudley cannot be relied on as prior art reference given that the current application is a continuation-in-part application of U.S. Patent Application Serial No. 09/703,753, filed November 1,2000, which is a continuation-in-part application of U.S. Patent Application Serial No. 09/651,777, filed August 30, 2000, which granted as US 6,503,894. Consequently, the disclosure of Labrie alone is insufficient to render the current claims obvious. Labrie teaches a combination therapy for the treatment of breast cancer and endometrial cancer by administering therapeutically effective amounts of an antiestrogen, at least

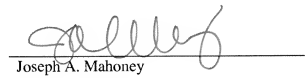
one androgenic compound, and an inhibitor of an enzyme in the sex steroid synthesis, which can be provided in a kit. Clearly, Labrie does not teach all of the limitations of the claimed invention – a method of treating or reducing the risk of developing a depressive disorder by administering to an area of skin a therapeutically effective amount of testosterone and the distinct pharmacokinetic profiles.. Therefore, Applicants submit that no *prima facie* case of obviousness exists.

CONCLUSION

For at least the foregoing reasons, it is respectfully submitted that the pending claims are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution. Further, none of Applicants' amendments are to be construed as dedicating any such subject matter to the public, and Applicants reserve all rights to pursue any such subject matter in this or a related patent application.

Kindly contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,



Joseph A. Mahoney
Reg. No. 38,956

CUSTOMER NUMBER 26565
MAYER, BROWN, ROWE & MAW LLP
P.O. Box 2828
Chicago, IL 60690-2828
Telephone: (312) 701-8286
Facsimile: (312) 706-9000